

AMENDMENTS TO THE CLAIMS

Claim 1 (previously presented): A method for treating myeloma, comprising:

(A) (a) providing an anti-IL-6 receptor antibody that inhibits signal transmission of IL-6 by blocking the binding of IL-6 ligand to IL-6 receptor,

wherein an anticancer therapeutic mechanism of the anti-IL-6 receptor antibody is inhibition of signal transmission of IL-6;

(b) providing a melphalan; and

(c) administering the melphalan in combination with the anti-IL-6 receptor antibody as part of a treatment regimen,

wherein the co-administration of melphalan and the anti-IL-6 receptor antibody has a higher (synergistic) therapeutic effect for myeloma than when the anti-IL-6 receptor antibody alone is administered or when the melphalan alone is administered; or

(B) the method of (A), wherein the anti-IL-6 receptor antibody and the melphalan are formulated in separate pharmaceutical compositions which are administered at different times or are administered at the same time, or the anti-IL-6 receptor antibody and the melphalan are formulated in one pharmaceutical composition.

Claim 2 (previously presented): The method according to claim 1, wherein the anti-IL-6 receptor antibody comprises a monoclonal antibody.

Claim 3 (previously presented): The method according to claim 2, wherein the monoclonal antibody comprises a PM-1 antibody deposited as FERM BP-2998.

Claim 4 (previously presented): The method according to claim 3, wherein the PM-1 antibody comprises a reshaped human PM-1 antibody.

Claim 5 (canceled)

Claim 6 (previously presented): The method according to claim 1, wherein (a) the melphalan is administered as an oral administration of 1 to 20 mg per day, every day or 1 to 6 times per week, or as high-dose intravenous injection or infusion, single or multiple doses of 20 to 200 mg/m².

Claim 7 (previously presented): A method for treating myeloma, comprising

(A) administering an anti-IL-6 receptor antibody in combination with a melphalan as part of a treatment regimen,

wherein an anticancer therapeutic mechanism of the anti-IL-6 receptor antibody is inhibition of signal transmission of IL-6,

and the anti-IL-6 receptor antibody or the melphalan is administered in an amount to have a higher (synergistic) therapeutic effect for myeloma than when the melphalan is administered alone, or when the anti-IL-6 receptor antibody is administered alone; or

(B) the method of (A), wherein the anti-IL-6 receptor antibody and the melphalan are formulated in separate pharmaceutical compositions which are administered at different times or are administered at the same time, or the anti-IL-6 receptor antibody and the melphalan are formulated in one pharmaceutical composition.

Claim 8 (previously presented): The method according to claim 7, wherein the anti-IL-6 receptor antibody comprises a monoclonal antibody.

Claim 9 (previously presented): The method according to claim 8, wherein the monoclonal antibody comprises a PM-1 antibody deposited as FERM BP-2998.

Claim 10 (previously presented): The method according to claim 9, wherein the PM-1 antibody comprises a reshaped human PM-1 antibody.

Claim 11 (canceled)

Claim 12 (previously presented): The method according to claim 7, wherein melphalan is formulated for oral administration, or for oral administration at 1 to 20 mg per day, every day or 1 to 6 times per week, or for high-dose intravenous injection or infusion, single or multiple doses of 20 to 200 mg/m².

Claim 13 (previously presented): The method of claim 7, wherein the melphalan is administered as an oral administration of 1 to 20 mg per day, every day or 1 to 6 times per week, or as high-dose intravenous injection or infusion, single or multiple doses of 20 to 200 mg/m².

Claim 14 (previously presented): The method of claim 7, wherein the pharmaceutical composition is or the pharmaceutical compositions are administered simultaneously with the anti-IL-6 receptor antibody, and the ratio, is, when combined with daily oral administration of melphalan, 0.01 to 1000 fold (weight ratio) relative to the dose of melphalan.

Claim 15 (previously presented): The method of claim 1, wherein the pharmaceutical composition is or the pharmaceutical compositions are administered orally, by intravenous injection, drip infusion, intraarterial injection, intramuscular injection, intratumor injection, intrathoracic injection, or intraperitoneal injection, either systemically or locally.

Claim 16 (previously presented): The method of claim 1, wherein the pharmaceutical composition or the pharmaceutical compositions comprising anti-IL-6 receptor antibody is administered parenterally, by intravenous injection, drip infusion, intramuscular injection, intraperitoneal injection, subcutaneous injection, either systemically or locally; or, is administered as local dosage-forms, external preparations, local injections; or, as external preparations, liniments, ointments, gel, cream, emulsions, and liquids, tapes, plaster tapes, patches, nebulas, sprays or powders.

Claim 17 (previously presented): A method for treating a myeloma comprising:

(A) (a) providing at least one pharmaceutical composition comprising separately or in combination:

(i) an anti-IL-6 receptor antibody that inhibits signal transmission of IL-6 by blocking the binding of IL-6 ligand to IL-6 receptor,

wherein an anticancer therapeutic mechanism of the anti-IL-6 receptor antibody is inhibition of signal transmission of IL-6, and

(ii) a melphalan; and

(b) administering to an individual in need thereof the pharmaceutical composition as part of a treatment regimen,

wherein the co-administration of melphalan and the anti-IL-6 receptor antibody has a higher (synergistic) therapeutic effect for myeloma than when the anti-IL-6 receptor antibody alone is administered or when the melphalan alone is administered; or

(B) the method of (A), wherein the anti-IL-6 receptor antibody and the melphalan are formulated in separate pharmaceutical compositions which are administered at different times or are administered at the same time, or the anti-IL-6 receptor antibody and the melphalan are formulated in one pharmaceutical composition.

Claim 18 (previously presented): The method of claim 1, wherein treating myeloma comprises a life elongation effect.

Claim 19 (previously presented): The method of claim 7, wherein treating myeloma comprises a life elongation effect.

Claim 20 (previously presented): The method of claim 17, wherein treating myeloma comprises a life elongation effect.

Claim 21 (previously presented): A method for treating a myeloma comprising:

(A) (a) providing at least one pharmaceutical composition comprising separately or in combination:

(i) a recombinant monoclonal anti-IL-6 receptor antibody that inhibits signal transmission of IL-6 by blocking the binding of IL-6 ligand to IL-6 receptor, and

(ii) a melphalan; and

(b) administering to an individual in need thereof the pharmaceutical composition as part of a treatment regimen, wherein the administration comprises at least in part intravenous administration of melphalan or the anti-IL-6 antibody,

wherein the co-administration of melphalan and the anti-IL-6 receptor antibody has a higher (synergistic) therapeutic effect for myeloma than when the anti-IL-6 receptor antibody alone is administered or when the melphalan alone is administered; or

(B) the method of (A), wherein the anti-IL-6 receptor antibody and the melphalan are formulated in separate pharmaceutical compositions which are administered at different times or are administered at the same time, or the anti-IL-6 receptor antibody and the melphalan are formulated in one pharmaceutical composition, and at least one of the formulations is an intravenous formulation.